PERRIGO®

July 20, 2001

7637 '01 JUL 20 A10 :27

Docket No. 98N-0337
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

APPLICATION FOR EXEMPTION

Subject: Clemastine Fumarate Tablets USP, 1.34 mg
ANDA 74-512

Docket No. 98N-0337 APPLICATION FOR EXEMPTION

Statement of Purpose

Pursuant to 21 CFR 201.66(e), Perrigo requests an exemption from 21 CFR 201.66(c) and (d) in the form of a temporary deferral of the implementation of the requirements of this regulation. This deferral is requested because there is not currently approved labeling in the Drug Facts format for the reference listed drug available to the Perrigo Company. The exemption would apply to all current and future SKUs of the drug product.

The reference listed drug for this ANDA is Tavist-1® Tablets (NDA 17-661).

Background of the Request

From the time that the final rule was issued in 1999, it has been the understanding of the Perrigo Company, through several contacts with the Office of Generic Drugs, that the Agency would not approve ANDA labeling formatted according to the requirements described in 21 CFR 201.66 until approved reference listed drug labeling similarly formatted was available. Perrigo further understands, based on these contacts, that in the absence of approved reference listed drug labeling in drug facts format, ANDA labeling could not be converted regardless of the May 2002 deadline.

We believe that it is the Office of Generic Drugs' position that Drug Facts and non-Drug Facts format labeling may not be 'the same' as required by the Food Drug and Cosmetic Act under part 505 (j)(2)(A), and in fact, that the ANDA holder cannot know if the labeling will be 'the same' until the reference listed drug labeling is available for comparison. Therefore, in order to ensure continuing compliance with both the statue and the regulation, a temporary deferral of the implementation date is required until approved reference listed drug labeling is available in Drug Facts format.

98N-0337

515 Eastern Avenue
Allegan, Michigan 49010
(616) 673-8451

APP 19

In a letter from Dr. Charles Ganley to the Consumer Healthcare Products Association dated August 9, 1999, it was recommended that ANDA holders submit a request for deferral in those cases where the reference listed drug has not received approval for labeling in the Drug Facts format in sufficient time to allow conversion of the ANDA product labeling by the regulatory compliance date.

"Templates" for Drug Facts Labeling

The Office of Generic Drugs has published in a February 2001 draft guidance, certain templates for drug facts labeling of particular drugs, and has since published additional templates for products for which there is not approved reference listed drug (RLD) labeling in Drug Facts format. The February 2001 draft guidance also made reference to the potential for ANDA applicants to submit changes to implement Drug Facts labeling in the absence of an approved reference listed drug in this format.

Our discussions as late as July 2001 with OGD representatives have verified that the presence of a published template does not confer any special status to a drug product in the absence of approved RLD labeling. OGD will not grant approval for a supplement to implement drug facts labeling for an OTC ANDA product before the approval of the RLD in the same format. Further, since labeling in drug facts format and non-drug facts format is not considered to be "the same", ANDA holders may not implement Drug Facts format labeling by way of an annual report. The potential finalization date and content of the February 2001 draft guidance is unknown.

Length of the Deferral Request

Due to the large number of store-brand private labels maintained by Perrigo for each ANDA OTC drug product, converting the labeling to Drug Facts format requires significant time and resources. For any drug product for which Drug Facts format labeling is not available as of the date of this letter, Perrigo is submitting a request for a temporary deferral of implementation.

At the time that approved Drug Facts format labeling becomes available for each RLD, Perrigo will immediately act to file a Changes Being Effected Supplement for approval of the new labeling in the relevant ANDA. The product will then be entered into our labeling conversion schedule. Due the length of time required to prepare labeling, submit a CBE supplement, and finally convert the labeling of a product, we anticipate that conversion for a particular product can be accomplished within approximately six months from the approval of the labeling supplement or twelve months from when the RLD labeling is first approved and available to Perrigo in Drug Facts format.

If the reference listed drug for this ANDA has approved labeling available in Drug Facts format by the compliance date of May 2002, then this deferral is not anticipated to be required beyond May 2003.

If there are any questions concerning this request, please contact me by phone at (616) 673-9745 or fax at (616) 673-7655. Thank you for your attention to this matter.

Sincerely,

L. PERRIGO COMPANY

Brian Schuster
Manager, ANDA Submissions

CC:
Gary Buehler, Director
Office of Generic Drugs
FDA/CDER
Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

APPLICATION TO MARKET A NEW DRUG, BIOLOGIC, OR AN ANTIBIOTIC DRUG FOR HUMAN USE

(Title 21, Code of Federal Regulations, 314 & 601)

Form Approved: OMB No. 0910-0338
Expiration Date: March 31, 2003
See OMB Statement on page 2.

FOR FDA USE ONLY

APPLICATION NUMBER

APPLICANT INFORMATION

NAME OF APPLICANT	DATE OF SUBMISSION
L. Perrigo Company	JUL 19 2001
TELEPHONE NO. (Include Area Code) 616- 673-8451	FACSIMILE (FAX) Number (Include Area Code) 616- 673-7655
APPLICANT ADDRESS *(Number, Street, City, State, Country, ZIP Code or Mail Code, and U.S. License number if previously issued):* 515 Eastern Ave. Allegan, MI 49010	AUTHORIZED U.S. AGENT NAME & ADDRESS *(Number, Street, City, State, ZIP Code, telephone & FAX number)* IF APPLICABLE

PRODUCT DESCRIPTION

NEW DRUG OR ANTIBIOTIC APPLICATION NUMBER, OR BIOLOGICS LICENSE APPLICATION NUMBER *(If previously issued)* 74-512

ESTABLISHED NAME *(e.g., Proper name, USP/USAN name)*	PROPRIETARY NAME *(trade name)* IF ANY
CLEMASTINE FUMARATE, USP	

CHEMICAL/BIOCHEMICAL/BLOOD PRODUCT NAME *(If any)*	CODE NAME *(If any)*
CLEMASTINE FUMARATE	282

DOSAGE FORM:	STRENGTHS:	ROUTE OF ADMINISTRATION:
TABLETS	1.34 mg	ORAL

(PROPOSED) INDICATION(S) FOR USE: FOR TEMPORARY RELIEF OF NASAL CONGESTION ASSOCIATED WITH UPPER RESPIRATORY ALLERGIES OR SINUSITIS WHEN ACCOMPANIED BY OTHER SYMPTOMS OF HAY FEVER OR ALLERGIES OR COMMON COLD, INCLUDING RUNNY NOSE, SNEEZING, ITCHY NOSE OR THROAT, OR ITCHY, WATERY EYES.

APPLICATION INFORMATION

APPLICATION TYPE
(check one) ☐ NEW DRUG APPLICATION (21 CFR 314.50) ☒ ABBREVIATED NEW DRUG APPLICATION (ANDA, 21 CFR 314.94)
☐ BIOLOGICS LICENSE APPLICATION (21 CFR part 601)

IF AN NDA, IDENTIFY THE APPROPRIATE TYPE ☐ 505 (b)(1) ☐ 505 (b)(2)

IF AN ANDA, or 505(b)(2), IDENTIFY THE REFERENCE LISTED DRUG PRODUCT THAT IS THE BASIS FOR THE SUBMISSION

Name of Drug	Holder of Approved Application
TAVIST-1(R) TABLETS	NOVARTIS

TYPE OF SUBMISSION *(check one)* ☐ ORIGINAL APPLICATION ☐ AMENDMENT TO A PENDING APPLICATION ☐ RESUBMISSION
☐ PRESUBMISSION ☐ ANNUAL REPORT ☐ ESTABLISHMENT DESCRIPTION SUPPLEMENT ☐ EFFICACY SUPPLEMENT
☐ LABELING SUPPLEMENT ☐ CHEMISTRY MANUFACTURING AND CONTROLS SUPPLEMENT ☒ OTHER

IF A SUBMISSION OR PARTIAL APPLICATION, PROVIDE LETTER DATE OF AGREEMENT TO PARTIAL SUBMISSION: _____

IF A SUPPLEMENT, IDENTIFY THE APPROPRIATE CATEGORY ☐ CBE ☐ CBE-30 ☐ Prior Approval (PA)

REASON FOR SUBMISSION
Request for exemption from 21 CFR 201.66 (OTC Labeling Format).

PROPOSED MARKETING STATUS *(check one)* ☐ PRESCRIPTION PRODUCT (Rx) ☒ OVER THE COUNTER PRODUCT (OTC)

NUMBER OF VOLUMES SUBMITTED 1 THIS APPLICATION IS ☒ PAPER ☐ PAPER AND ELECTRONIC ☐ ELECTRONIC

ESTABLISHMENT INFORMATION (Full establishment information should be provided in the body of the Application.)
Provide locations of all manufacturing, packaging and control sites for drug substance and drug product (continuation sheets may be used if necessary). Include name, address, contact, telephone number, registration number (CFN), DMF number, and manufacturing steps and/or type of testing (e.g., Final dosage form, Stability/testing) conducted at the site. Please indicate whether the site is ready for inspection or, if not, when it will be ready.

Cross References (list related License Applications, INDs, NDAs, PMAs, 510(k)s, IDEs, BMFs, and DMFs referenced in the current application)

NDA# 17-661

This application contains the following items: *(Check all that apply)*

☐	1. *Index*	
☐	2. Labeling *(check one)*	☐ Draft Labeling ☐ Final Printed Labeling
☐	3. Summary (21 CFR 314.50(c))	
☐	4. *Chemistry section*	
☐	A. Chemistry, manufacturing, and controls information (e.g., 21 CFR 314.50(d)(1); 21 CFR 601.2)	
☐	B. Samples (21 CFR 314.50(e)(1); 21 CFR 601.2 (a)) (Submit only upon FDA's request)	
☐	C. *Methods validation package (e.g., 21 CFR 314.50(e)(2)(i); 21 CFR 601.2)*	
☐	5. Nonclinical pharmacology and toxicology section (e.g., 21 CFR 314.50(d)(2); 21 CFR 601.2)	
☐	6. Human pharmacokinetics and bioavailability section (e.g., 21 CFR 314.50(d)(3); 21 CFR 601.2)	
☐	7. Clinical Microbiology (e.g., 21 CFR 314.50(d)(4))	
☐	8. Clinical data section (e.g., 21 CFR 314.50(d)(5); 21 CFR 601.2)	
☐	9. Safety update report (e.g., 21 CFR 314.50(d)(5)(vi)(b); 21 CFR 601.2)	
☐	10. Statistical section (e.g., 21 CFR 314.50(d)(6); 21 CFR 601.2)	
☐	11. Case report tabulations (e.g., 21 CFR 314.50(f)(1); 21 CFR 601.2)	
☐	12. Case report forms (e.g., 21 CFR 314.50(f)(2); 21 CFR 601.2)	
☐	13. Patent information on any patent which claims the drug (21 U.S.C. 355(b) or (c))	
☐	14. A patent certification with respect to any patent which claims the drug (21 U.S.C.355(b)(2) or (j)(2)(A)	
☐	15. Establishment description (21 CFR Part 600, if applicable)	
☐	16. Debarment certification (FD&C Act 306(k)(1))	
☐	17. Field copy certification (21 CFR 314.50(k)(3))	
☐	18. User Fee Cover Sheet (Form FDA 3397)	
☐	19. Financial Information (21 CFR Part 54)	
☒	20. OTHER *(Specify)* Application for exemption	

CERTIFICATION

I agree to update this application with new safety information about the product that may reasonably affect the statement of contraindications, warnings, precautions, or adverse reactions in the draft labeling. I agree to submit safety update reports as provided for by regulation or as requested by FDA. If this application is approved, I agree to comply with all applicable laws and regulations that apply to approved applications, including, but not limited to the following:

1. Good manufacturing practice regulations in 21 CFR Parts 210, 211or applicable regulations, Parts 606, and/or 820.
2. *Biological establishment standards in 21 CFR Part 600.*
3. Labeling regulations in 21 CFR Parts 201, 606, 610, 660 and/or 809.
4. In the case of a prescription drug or biological product, prescription drug advertising regulations in 21 CFR 202.
5. Regulations on making changes in application in FD&C Act Section 506A, 21 CFR 314.71, 314.72, 314.97, 314.99, and 601.12.
6. Regulations on Reports in 21 CFR 314.80, 314.81, 600.80 and 600.81.
7. Local, state and Federal environmental impact laws.

If this application applies to a drug product that FDA has proposed for scheduling under the Controlled Substances Act, I agree not to market the product until the Drug Enforcement Administration makes a final scheduling decision.

The data and information in this submission have been review and, to the best of my knowledge are certified to be true and accurate.

Warning: A willfully false statement is a criminal offense, U.S. Code, title 18, section 1001.

SIGNATURE OF RESPONSIBLE OFFICIAL OR AGENT	TYPED NAME AND TITLE	DATE
Brian Schuster	Brian R. Schuster, Regulatory Affairs, Manager	JUL 19 2001

ADDRESS *(Street, City, State, and ZIP Code)*	TELEPHONE NUMBER
515 Eastern Ave., Allegan,MI 49010	616-673-8451

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Department of Health and Human Services
Food and Drug Administration
CBER, HFM-99
1401 Rockville Pike
Rockville, MD 20852-1448

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